



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OCT 8 1987

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Amended Frozen Storage Stability Study Protocol for
Maneb and ETU on Raw Agricultural Commodities (RCB
No. 2846) - No Accession Number

FROM: Martin F. Kovacs, Jr., Ph.D., Chemist
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and

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THRU: Charles L. Trichilo, Ph.D., Chief
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RCB has been requested by the DCI staff to review and develop an appropriate response to the September 8, 1987 letter from Joseph D. Panetta, Chairman, Maneb Task Force (MTF) to Joan Warshawsky, SRB/RD, and to comment on a revised August 21, 1987 protocol for storage stability. The letter asked for the inclusion of spinach in the RAC storage stability study protocol.

Summary of Protocol Deficiencies Remaining to be Resolved
(as also delineated in RCB's July 31, 1987 memorandum - RCB No. 2535).

1. The revised June 19, 1987 draft storage stability study protocol "Determination of the Stability of Maneb and ETU Residues in Processed Commodities,"

Morse Laboratories, Inc., Sacramento, CA is acceptable provided the registrant submits residue data on the following apple processed fractions: fresh juice, cooked/canned juice, wet pomace, dry pomace, cooked/canned applesauce, and strained baby food.

2. The MTF has not addressed the outstanding protocol deficiencies cited in the May 28, 1987 RCB memorandum for the following protocols:
 - a. Draft protocol "Pilot Study for the Determination of the Stability of Maneb and Ethylene Thiourea Residues in Stored Frozen Samples of Milk, Eggs, Beef Tissues, and Poultry Tissues," prepared by Hazleton Laboratories America, Inc., Madison, WI 53704 dated March 24, 1987.
 - b. Draft protocol "Determination of the Stability of Maneb Residues in Stored Frozen Samples of Milk, Eggs, Beef Tissues, and Poultry Tissues," prepared by Hazleton Laboratories America, Inc., Madison, WI 53704 dated March 24, 1987.

Conclusions With Respect to the Revised RAC Protocol

RCB has no objections to placing spinach back on the current matrix list of crops for which storage stability studies are to be conducted, thereby resulting in a total of five commodities now to be tested. The registrant should be advised; however, that it was EPA's original intent in the March 31, 1987 DCI Notice (and still is) that only four commodities need to be tested: apples, spinach, lettuce, and tomatoes. The inclusion of potatoes on the matrix list is now at the registrant's own option.

As a result of the current submission, only those remaining deficiencies cited above under "Summary of Protocol Deficiencies Remaining to be Resolved" need to be resolved.

Recommendations

1. The registrant must submit a plan for residue data on the following apple processed fractions in a revised storage stability study protocol for processed commodities: fresh juice, cooked/canned juice, wet pomace, dry pomace, cooked/canned applesauce, and strained baby food.

2. The registrant must submit revised protocols for animal commodity storage stability studies to address the outstanding deficiencies cited in RCB's May 28, 1987 memorandum.
3. This review should be sent to the registrant as soon as possible so that our comments and suggestions may be incorporated into final protocols for frozen storage stability studies on processed food and animal commodities.

Note to PM: The registrant should be advised that it was (see EPA's March 31, 1987 DCI Notice), and still is, EPA's requirement that RAC storage stability studies need to be conducted on four commodities: apples, spinach, lettuce, and tomatoes. The current retention of potatoes on the matrix list of crops to be studied is at the registrant's own option.

Present Considerations

The recommended protocol revisions as first delineated in RCB's May 28, 1987 memorandum are given below followed by the registrant's original remarks, RCB's original comments in the May 28, 1987 memorandum, then by the registrant's subsequent remarks, in RCB's June 26, 1987 memorandum, RCB's subsequent comments in RCB's June 26 and July 31, 1987 memoranda, and finally by the registrant's current remarks, and RCB's current comments.

DRAFT STORAGE STABILITY STUDY PROTOCOL FOR MANEB AND ETU ON RAW AGRICULTURAL COMMODITIES

Test Matrix

Registrant's Original Remarks

This study will be conducted on apples, spinach, lettuce, and tomatoes.

RCB's Original Comments

We have no objections to test matrix

Registrant's Subsequent Remarks

Since it has been decided by the MTF not to include spinach on the maneb label and therefore not conduct any residue work pertaining to spinach, the MTF hereby requests that spinach be replaced on the RAC storage stability study protocol with another crop from another vegetable group.

Because lettuce belongs to the same family as spinach, the MTF proposes to use a crop from the root and tuber vegetable group. The alternative crop would be potatoes.

RCB's Subsequent Comments

RCB's Comments/Conclusions paragraph of the M.F. Kovacs, Jr., June 26, 1987 memorandum re: "Protocol Change to Maneb and ETU Storage Stability Studies in the March 31, 1987 Maneb DCI" stated "RCB has no objections to the Maneb Task Force's selection of potatoes as an alternative crop, to spinach, for conducting the RAC storage stability studies as required by the 3/31/87 Maneb DCI."

This memorandum was prompted by the June 16, 1987 letter by Joseph D. Panetta, Chairman, MTF, to Joan Warshawsky, EPA/RD/SRB, requesting replacement of spinach in the RAC storage stability study protocol with potatoes since the MTF had decided not to include spinach on the maneb label and therefore not conduct any residue work pertaining to spinach.

RCB recommends that the commodity "potatoes" be added to the current matrix list of crops to be studied. However, if the registrant (MTF) subsequently decides to include spinach on the maneb label then spinach must be substituted for potatoes in the matrix of commodities to be studied.

Registrant's Current Comments

EPA is requiring the MTF to analyze five crops in this study which will serve to represent all raw agricultural commodities analyzed for the Data Call-In. The five crops are apples, potatoes, lettuce, tomatoes, and spinach.

Matrix

This study will be conducted on apples, potatoes, lettuce, tomatoes, and spinach.

RCB's Current Comments

The registrant should be advised that EPA's March 31, 1987 DCI Notice for Maneb Storage Stability/Residue Data originally recommended that only four commodities be tested: apples, spinach, lettuce, and tomatoes. EPA has never required that five commodities be tested as now stated by the registrant. RCB's June 26, 1987 memorandum clearly stated no objections to the MTF selection of potatoes as an alternative crop to spinach and in RCB's July 31, 1987 memorandum it was further stated that if the registrant (MTF) subsequently

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decides to include spinach on the maneb label (as is now the case) then spinach must be substituted for potatoes in the matrix of commodities to be studied. RCB, however, has no objections to placing spinach back on the current matrix list of crops to be studied. The current inclusion of potatoes on the matrix list is now at the registrant's own option.

cc: W. Boodee, E. Zager, Reviewer - M. Kovacs, S.F., R.F.,
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